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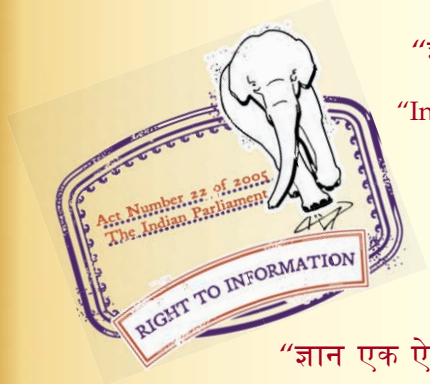
"जानने का अधिकार, जीने का अधिकार"
Mazdoor Kisan Shakti Sangathan
"The Right to Information, The Right to Live"

"पुराने को छोड नये के तरफ"
Jawaharlal Nehru
"Step Out From the Old to the New"

IS 11043 (1984): Needle, Epidural [MHD 1: Surgical Instruments]



"ज्ञान से एक नये भारत का निर्माण"
Satyanarayan Gangaram Pitroda
"Invent a New India Using Knowledge"

"ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है"
Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

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(Reaffirmed 2001)

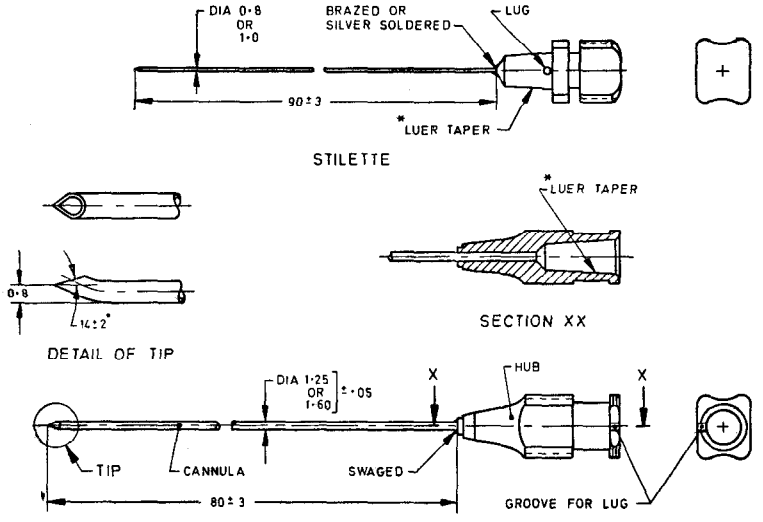
Indian Standard

SPECIFICATION FOR NEEDLE, EPIDURAL

Surgical Instruments Sectional Committee, CPDC 11; Needles and Hollow Instruments Subcommittee, CPDC 11:2 [Ref : Doc : CPDC 11 (1727)]

1. Scope — Dimensional and other requirements of epidural needles used for injecting fluid in the spine.

2. Shape and Dimensions — As shown in Fig. 1.



*See IS : 3234-1979 ' Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type (*first revision*) '.

All dimensions in millimetres.

FIG. 1 NEEDLE, EPIDURAL

3. Material

3.1 *Cannula* — The cannula shall be made from stainless steel drawn tubing. The stainless steel shall conform to Designation 04Cr18Ni11, 07Cr18Ni9, 04Cr17Ni12Mo2 or 04Cr17Ni12Mo2Ti20 of IS : 1570 (Part 5)-1972 ' Schedules for wrought steel: Part 5 Stainless and heat resisting steels (*first revision*) '.

3.2 *Hub* — The hub shall be made from free cutting brass rod or bar conforming to IS : 319-1974 ' Specification for free cutting brass rods and sections (*third revision*) '.

3.3 *Stilette Wire* — Stilette wire shall be stainless steel wire and supplied one for each needle.

4. Conical Fitting — The conical fitting shall be of the Luer type and shall be in accordance with IS : 3234-1979 ' Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type (*first revision*) '.

5. Construction

5.1 The cannula shall be pushed well into the cavity of the hub but not extending into the conical portion and securely swaged. The cannula and the hub shall be concentric and well aligned.

5.2 *Point of the Needle* — The needle point shall have a slight curvature as shown in Fig. 1. The point shall have a bevel of 30° ± 2°. The point shall be sharpened on 3 aspects as shown in Fig. 1. It shall be sharp, well defined and free from any feather edge, irregularity and burrs when examined under 10 × magnification.

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6. Finish

6.1 Cannula shall be smooth both outside and inside and free from pits, cracks, tool marks, burrs embedded foreign matter and other surface defects.

6.2 The hub shall be free from pits, burrs, cracks, sharp edges, tool marks, roughness and other surface defects. It shall be plated both inside and outside chromium over nickel conforming to service Grade No. 2 of IS : 4827-1968 'Specification for electroplated coatings of nickel and chromium on copper and copper alloys' and polished. The plating shall be such as to withstand the corrosion test given at **7.7.**

6.3 Stilette wire shall be smooth, bright and free from foreign matter and shall slide smoothly into the cannula. The point of the needle shall coincide with point of the stilette. The stilette wire shall be brazed or silver soldered to a hub as shown in Fig. 1.

6.3.1 The stilette button shall be provided with a tongue or other means of location with the needle hub so as to position the end of the stilette within the needle point.

6.3.2 The stilette when correctly seated shall not fall out of the needle under its over weight but it shall be freely removable in use.

7. Tests

7.1 *Leakage Test* — Fit the needle to a tested syringe and connect the syringe to a water source on which pressure could be exerted. Run the water through the needle to eliminate air, seal the assembly outlet and bring the water pressure to 300 kPa. Maintain the pressure for 30 seconds. There shall be no leakage sufficient to form a falling drop. The conical fitting under test shall be horizontal.

7.2 *Sharpness of Needle Point* — Take an aluminium foil 0·02 mm thick and clean it with alcohol or benzene and mount suitably so that it is spread taut and the needle may penetrate vertically. Stand the needle with its point touching the foil ensuring that the weight of the needle did not act on foil. Apply load on the hub gently starting with one gram. Then increase the load gradually, so as to reach the test load in about 30 seconds. The needle shall penetrate the aluminium foil with a test load not exceeding 50 g.

7.3 *Elasticity* — Clamp the hub rigidly and deflect the cannula through an angle given in Table 1, force being applied at a contact distance as specified in Table 1. The needle shall show no permanent set or damage.

7.4 *Reverse Bend Test* — Clamp the hub firmly and apply force at points whose contact distance is in accordance with the requirements of Table 1, so that the cannula is deflected through the degrees specified, and reverse the test in the opposite direction. Perform the test for 20 complete cycles and examine the needle. The needle shall have suffered no damage and shall not have developed fracture.

7.5 *Stiffness* — Support the cannula of the needle at two places giving a span as shown in Table 1, and load it centrally as specified. The deflection of cannula shall be not greater than the limits given in Table 1.

7.6 *Security of Swaging* — The swaging of the cannula with the hub shall be tested by applying for one minute a pull of magnitude given in Table 1. The cannula shall not come out of the hub and it shall not become loose.

7.7 *Corrosion Resistance* — The complete needle shall be immersed in a 10 percent solution of citric acid at room temperature for 5 hours. It shall then be boiled in distilled water for 30 minutes. The water and the immersed needle shall then be allowed to cool and shall remain at room temperature for 48 hours. The cannula or hub shall show no corrosion after having been dried by evaporation. The test shall be conducted in a glass container.

7.8 *Freedom from Foreign Matter* — The cannula and the hub shall be examined under good illumination with a magnifying lens; they shall be free from foreign matter, metal particles or chips, pits, burrs and other defects.

8. Marking — The hub of the needle shall be marked with the diameter of the needle and the manufacturer's identification mark.

8.1 *ISI Certification Marking* — Details available with the Indian Standards Institution.

9. Packing — Needles shall be packed in accordance with the best trade practices and supplied with equal number of stilettes also packed suitably. The packet shall be marked with manufacturer's name and the purpose for which the needle is to be used. Alternatively the needles shall be packed as agreed to between the purchaser and the supplier.

TABLE 1 TESTS

(*Clauses* 7.3, 7.4, 7.5 and 7.6)

Diameter of Cannula	Elasticity		Reverse Bend Test		Stiffness			Security of Swaging Pull to be Applied
	Contact Distance from Hub	Angle of Bend	Contact Distance from Hub	Deflection	Separation of Test Edges	Load	Deflection, *Max*	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
mm	mm	degrees	mm	degrees	mm	g	mm	kg
1·25	32	12	32	25	25	2 000	2·5	6·5
1·60	32	9	—	—	25	2 000	2·5	9·0

EXPLANATORY NOTE

In the preparation of this standard assistance has been derived from BS 6196 : 1982 'Specification for sterile epidural catheters and their introducer needles for single use', issued by the British Standards Institution.

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